



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
---------------	-------------	----------------------	---------------------

08/278,601 07/21/94 KNIFE

D	DEC1363A
EXAMINER	

CAPUTA, A

ART UNIT	PAPER NUMBER
----------	--------------

9

18M2/0122

DAVID E BROOK
HAMILTON BROOK SMITH AND REYNOLDS
TWO MILTIA DRIVE
LEXINGTON MA 02173

1806

DATE MAILED:

01/22/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/13/95
9/2/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input checked="" type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. <u>5, 5</u> | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-32 are pending in the application.

Of the above, claims 27, 28 are withdrawn from consideration.

2. ☐ Claims have been cancelled.

3. ☐ Claims are allowed.

4. ☒ Claims 1-26, 29-32 are rejected.

5. ☐ Claims are objected to.

6. ☒ Claims 1-32 are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Part III DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-30 and 32, drawn to mutated herpesvirus vaccine or therapeutic composition, classified in Class 424, subclass 231.1.

Group II. Claim 31, drawn to recombinant viral vaccine encoding heterologous genes, classified in Class 424, subclass 199.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II both drawn to vaccines differ in structure and in utility, because in one case the virus induces a response against the herpesvirus alone, whereas in the other case the virus is used as a vector to induce a response against a non-herpes virus. Therefore, the viruses of Group I and II are seen as patentably distinct.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. a mutant with a mutation in the gene encoding the ICP8 protein
- b. a mutant with a mutation in the gene ICP27 protein.

These species are distinct since a mutant with a mutation in gene encoding the ICP8 protein differs in immunogenicity and

chemical structure from a mutant which has a mutation in the gene encoding the ICP27 gene.

Applicant is required under 35 U.S.C. § 121 to elect a species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-26, 31, and 32 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

4. During a telephone conversation with Carolyn Elmore on October 3, 1995 a provisional election was made with traverse to prosecute the invention of Group I, directed to the ICP8 species. Affirmation of this election must be made by applicant in responding to this Office action.

Upon further consideration by the Examiner, the restriction requirement made above is withdrawn. However, the election of species as set forth above is maintained. Claims 27 and 28 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 1-26, 31, and 32 which are generic will be examined only to the

extent said claims read on a herpesvirus with a mutation in the gene encoding the IPC8 protein.

Note: It is noted by the Examiner that claim 4 is directed to a mutation in the gene encoding the ICP28 protein. From examination of the specification it would appear this is a typographical error and should be ICP27. Clarification is requested.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a

terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-26, and 29-32 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-26, and 29-32 of copending application Serial No. 08/179,106. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

7. Claims 1-26, and 29-32 of this application conflict with claims 1-26, and 29-32 of application serial number 08/179,106. 37 C.F.R. § 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See M.P.E.P. § 822.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach one of ordinary skill in the art how to make and/or use the claimed invention, i.e. failing to provide an enabling disclosure.

The specification is not enabled for using the claimed invention because there is insufficient guidance of how to use the elected mutant herpesvirus as a vaccine. Roizman teach that an effective herpes virus should meet several criteria. These criteria include: a) avirulence, b) stability (the virus should not revert to the virulent state), c) the mutant should provide immunity to several viral challenges and, d) the mutant should have low pathogenicity and should not be capable of transforming host cells. Since the specification does not set forth the elected species meet the criteria as set forth by Roizman (i.e. provides immunity to several viral challenges) and the claimed invention encompass any mutated herpesvirus which a mutation of the gene encoding the ICP8 protein, and it would not be expected that all mutants of herpesvirus comprising deletions or substitutions of the gene encoding the ICP8 protein would meet the criteria as set forth by Roizman, it would be unpredictable and be an undue burden for a skilled artisan to determine how to use the elected mutant herpesvirus as a vaccine.

Further, a deposit of herpesvirus d301 is required to enable the invention of claim 30. Because it is not clear that a herpesvirus possessing the identical structure and functional properties of the recited herpesvirus d301 is known and publicly available or can be reproducibly isolated without undue experimentation, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above herpesvirus d301, one skilled in the art could not be assured of the ability to practice the invention as claimed. A deposit of the claimed herpesvirus d301 would satisfy the requirements of 35 USC 112 first paragraph. See CFR 1.801-1.809.

In addition, the identifying information set forth in 37 CFR 1.809 (d) should be added to the specification. See CFR 1.803-1.809 for additional explanation of these requirements.

9. Claims 1-26, and 29-32 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

11. Claims 1-26, and 29-32 are rejected under 35 U.S.C. § 103 as being unpatentable over Roizman and further in view of Gao et al. and Weller et al.

Roizman teaches recombinant herpes simplex virus genomes which contain mutations in portions of the genome responsible for

virulence (see abstract). Roizman teaches the viruses may be useful not only as vaccines but as vectors for insertion of foreign genes (see Column 2, lines 26-39). With respect to the preparation of mutant recombinant vaccines, Roizman states that an effective herpes virus should meet several criteria. These criteria include: a) avirulence, b) stability (the virus should not revert to the virulent state), c) the mutant should provide immunity to several viral challenges and, d) the mutant should have low pathogenicity and should not be capable of transforming host cells). Roizman does not teach a mutant incapable of replication.

Gao et al. describe several mutant herpesvirus of the infected cell protein 8 (ICP8)* which lack the ability to replicate and bind DNA (see abstract, page 5259, figure 5, and Table 4). Gao et al. describes a mutant d301 from HSV which is replication defective (see Figure 5, lane 11). The importance of IPC8 gene product in DNA binding which results in replication and transformation is suggested by Weller et al. (see page 364).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Roizman on mutant herpesvirus suitable for vaccine and vector purposes with the teachings of Gao et al. on mutants of the ICP8 defective in DNA binding and replication and Weller et al. on the suggested role of DNA binding protein in transformation and tumorigenicity to develop a vaccine which includes a mutant herpesvirus of the infected cell protein 8 (ICP 8) or mutant herpes virus coding for one or more heterologous genes.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Anthony C. Caputa, whose telephone number is (703)-308-3995. The examiner can be reached on Monday-Thursday from 8:30 AM-6:00 PM. The examiner can be reached on alternate Fridays. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703)-308-0196.

Serial Number: 08/278,601
Art Unit: 1806

-9-

Papers related to this application may be submitted to Group 1806 by facsimile transmission. Papers should be faxed to Group 1806 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703)-305-3014.

Anthony C. J.
Anthony C. Caputa, Ph.D.
January 6, 1996

**ANTHONY C. CAPUTA
PATENT EXAMINER
GROUP 1800**